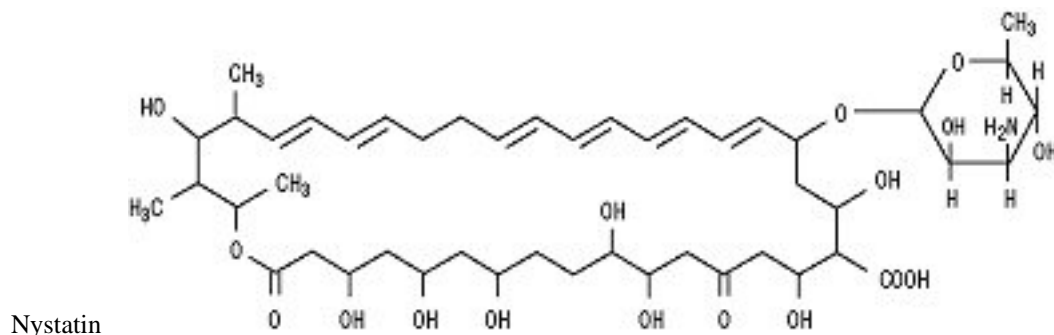


MYCOSTATIN - nystatin cream
MYCOSTATIN - nystatin powder
Bristol-Myers Squibb Company

FOR TOPICAL USE ONLY • NOT FOR OPHTHALMIC USE

DESCRIPTION

Nystatin is a polyene antifungal antibiotic obtained from *Streptomyces noursei*.
Structural formula:



Mycostatin[®] Cream (Nystatin Cream) and Mycostatin[®] Topical Powder (Nystatin Topical Powder) are for dermatologic use.

MYCOSTATIN[®] (Nystatin) Cream for topical use, contains 100,000 USP nystatin units per gram. Inactive ingredients: aluminum hydroxide concentrated wet gel, titanium dioxide, propylene glycol, cetearyl alcohol (and) cetareth-20, white petrolatum, sorbitol solution, glyceryl monostearate, polyethylene glycol monostearate, sorbic acid and simethicone.

MYCOSTATIN[®] (Nystatin) Topical Powder contains 100,000 USP nystatin units per gram dispersed in talc.

CLINICAL PHARMACOLOGY

Pharmacokinetics

Nystatin is not absorbed from intact skin or mucous membrane.

Microbiology

Nystatin is an antibiotic which is both fungistatic and fungicidal *in vitro* against a wide variety of yeasts and yeast-like fungi, including *Candida albicans*, *C. parapsilosis*, *C. tropicalis*, *C. guilliermondi*, *C. pseudotropicalis*, *C. krusei*, *Torulopsis glabrata*, *Tricophyton rubrum*, *T. mentagrophytes*.

Nystatin acts by binding to sterols in the cell membrane of susceptible species resulting in a change in membrane permeability and the subsequent leakage of intracellular components. On repeated subculturing with increasing levels of nystatin, *Candida albicans* does not develop resistance to nystatin. Generally, resistance to nystatin does not develop during therapy. However, other species of *Candida* (*C. tropicalis*, *C. guilliermondi*, *C. krusei*, and *C. stellatoidea*) become quite resistant on treatment with nystatin and simultaneously become cross resistant to amphotericin as well. This resistance is lost when the antibiotic is removed.

Nystatin exhibits no appreciable activity against bacteria, protozoa, or viruses.

INDICATIONS AND USAGE

Nystatin topical preparations are indicated in the treatment of cutaneous or mucocutaneous mycotic infections caused by *Candida albicans* and other susceptible *Candida* species.

These preparations are not indicated for systemic, oral, intravaginal or ophthalmic use.

CONTRAINDICATIONS

Nystatin topical preparations are contraindicated in patients with a history of hypersensitivity to **any** of their components.

PRECAUTIONS

General

Nystatin, topical preparations should not be used for the treatment of systemic, oral, intravaginal or ophthalmic infections.

If irritation or sensitization develops, treatment should be discontinued and appropriate measures taken as indicated. It is recommended that KOH smears, cultures, or other diagnostic methods be used to confirm the diagnosis of cutaneous or mucocutaneous candidiasis and to rule out infection caused by other pathogens.

INFORMATION FOR THE PATIENT

Patients using these medications should receive the following information and instructions:

1. The patient should be instructed to use these medications as directed (including the replacement of missed doses). These medications are not for any disorder other than that for which they are prescribed.
2. Even if symptomatic relief occurs within the first few days of treatment, the patient should be advised not to interrupt or discontinue therapy until the prescribed course of treatment is completed.
3. If symptoms of irritation develop, the patient should be advised to notify the physician promptly.

Laboratory Tests

If there is a lack of therapeutic response, KOH smears, cultures, or other diagnostic methods should be repeated.

Carcinogenesis, Mutagenesis, Impairment of Fertility

No long-term animal studies have been performed to evaluate the carcinogenic potential of nystatin. No studies have been performed to determine the mutagenicity of nystatin or its effects on male or female fertility.

Pregnancy: Teratogenic Effects

Category C. Animal reproduction studies have not been conducted with any nystatin topical preparation. It also is not known whether these preparations can cause fetal harm when used by a pregnant woman or can affect reproductive capacity. Nystatin topical preparations should be prescribed for a pregnant woman only if the potential benefit to the mother outweighs the potential risk to the fetus.

Nursing Mothers

It is not known whether nystatin is excreted in human milk. Caution should be exercised when nystatin is prescribed for a nursing woman.

Pediatric Use

Safety and effectiveness have been established in the pediatric population from birth to 16 years.
(See **DOSAGE AND ADMINISTRATION**.)

Geriatric Use

Clinical studies with MYCOSTATIN (Nystatin) Cream and MYCOSTATIN (Nystatin) Topical Powder did not include sufficient numbers of subjects aged 65 years and older to determine whether they respond differently than younger subjects. Other reported clinical experience has not identified differences in responses between elderly and younger patients, but greater sensitivity of some older individuals cannot be ruled out.

ADVERSE REACTIONS

The frequency of adverse events reported in patients using Mycostatin[®] preparations is less than 0.1%. The more common events that were reported include allergic reactions, burning, itching, rash, eczema, and pain on application.
(See **PRECAUTIONS: General**.)

DOSAGE AND ADMINISTRATION

Very moist lesions are best treated with the topical dusting powder.

MYCOSTATIN[®] Cream

Adults and Pediatric Patients (Neonates and Older):

Apply liberally to affected areas twice daily or as indicated until healing is complete.

MYCOSTATIN[®] Topical Powder

Adults and Pediatric Patients (Neonates and Older):

Apply to candidal lesions two or three times daily until healing is complete. For fungal infection of the feet caused by *Candida* species, the powder should be dusted on the feet, as well as, in all foot wear.

HOW SUPPLIED

MYCOSTATIN[®] Cream: 100,000 units nystatin per gram in an aqueous, perfumed vanishing cream base, in 30 g (NDC 0003-0579-31) tubes.

MYCOSTATIN[®] Topical Powder: 100,000 units nystatin per gram in 15 g (NDC 0003-0593-20) plastic squeeze bottles.

ALSO AVAILABLE

MYCOSTATIN[®] (Nystatin) is also available as vaginal tablets and in oral formulations (pastilles, suspension, tablets). See package inserts for complete prescribing information.

STORAGE

MYCOSTATIN[®] Cream: Store at room temperature, avoid freezing.

MYCOSTATIN[®] Topical Powder: Store at room temperature, avoid excessive heat (40° C/104° F). Keep tightly closed.

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